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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/702,096	11/05/2003	Stephen D. Kuslich	C364.104.101(19478-00005)	6813
24113 7590 09/14/2007 PATTERSON, THUENTE, SKAAR & CHRISTENSEN, P.A. 4800 IDS CENTER 80 SOUTH 8TH STREET MINNEAPOLIS, MN 55402-2100			EXAMINER STEWART, ALVIN J	
			ART UNIT 3738	PAPER NUMBER
			MAIL DATE 09/14/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/702,096

Applicant(s)

KUSLICH, STEPHEN D.

Examiner

Alvin J. Stewart

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 6/29/07.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,8,16,17,19,23-31 and 33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,8,16,17,19,23-31 and 33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments filed 6/29/07 have been fully considered but they are not persuasive.

After a careful examination of the Applicant's remarks the Examiner disagrees with the Applicant's representative point of view. For example, the Applicant's representative discloses, in the remarks, the Belef reference does not teach or disclose tissue-promoting material. In particular none of the cited paragraphs disclose any fill material that will promote tissue growth.

However, the Belef reference in paragraph 61, clearly disclose growth factors that are capable of stimulating cellular proliferation and cellular differentiation. Additionally, in paragraph 64, Belef discloses a different embodiment having a bioabsorbable bladder that overtime the implant is absorbed by the patient's body after sufficient time for the annulus fibrosis to substantially heal. Therefore, if the implant is replaced by the patient's tissue over time, then, the growth factors and the rest of the fill materials (over time) promote the growth of tissue.

Finally, paragraph 65, discloses healing-promoting materials, therefore, discloses tissue promoting materials. For the above reasons, the Examiner makes the rejection final.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

Art Unit: 3738

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, 8, 16, 17, 19, 23-31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Belef et al US Pub. 2002/0147496 A1 in view of Pernia et al US Patent 5,634,945.

Belef et al discloses a system comprising an injection tube (14) having a diameter similar to the partially excavated cavity (96), a volume of tissue promoting material ( $\pi$  61) and an insertion device coupled to the injection tube (see  $\pi$  62 & 64). Regarding claims 2 and 8, see paragraph 65. However, Belef et al does not disclose one or more strands of the tissue promoting material.

Pernia et al disclose a biological filler comprising a plurality of strands for the purpose of replacing soft tissue which is available, cost effective and not likely to suffer rejection or complications from its use (see col. 1, lines 50-56, lines 61-66; col. 2, lines 39-42, lines 61-67; and col. 3, lines 1-20).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the filler of the Belef et al reference with the biocompatible filler of the Pernia et al reference in order to provide a material for use as a replacement for soft tissue which is available, cost effective, and not likely to suffer rejection or complications from its use.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

Art Unit: 3738

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J. Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*A. Stewart*  
**ALVIN J. STEWART**  
**PRIMARY EXAMINER**

Art Unit 3738

September 7, 2007.